UNITED STATES PATENT AND TRADEMARK OFFICE

7.

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,421	01/18/2002	John E. Sims	3086-A	6827

22932 7590 08/31/2006

IMMUNEX CORPORATION
LAW DEPARTMENT
1201 AMGEN COURT WEST
SEATTLE, WA 98119

EXAMINER
JIANG, DONG

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,421	SIMS ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 6-15* is/are pending in the application.

4a) Of the above claim(s) *2, 3 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,7 and 9-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-3 and 6-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/2/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's response filed on 02 June 2006 is acknowledged.

Currently, claims 1-3 and 6-15 are pending, and claims 1, 6, 7 and 9-15 are under consideration.

Formal Matters:

Information Disclosure Statement

The information disclosure statement filed 02 June 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6, 9-12, 14 and 15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ho et al., WO 00/56771 (28 September 2000), and in view of Torigoe et al., US6,600,022 B1, for the same reasons of record set forth in the previous Office Actions mailed on 12/3/04 and 8/13/05.

Applicants argument filed on 02 June 2006 has been fully considered, but is not deemed persuasive for reasons below.

At page 2 of the response, the applicant argues that in light of the Ho and Torigoe references at the time of filing, one of skill in the art would not have had a reasonable expectation that an antibody binding the IL-18R would be successful in treating the indicated diseases; that, citing the Dayer reference (J. Clin. Invest., 1999, 104:1337-39), one should not conclude that blocking IL-18 would help in treating, for example, rheumatoid arthritis (RA); and that neither Ho nor Torigoe quells the speculation regarding the *in vivo* effects of blocking IL-18, thus, at the time of filing, one of skill in the art could not reasonably conclude that blocking IL-18 in vivo by targeting the IL-18R would have efficacy in treating a medical disorder as claimed. Applicants further argue, at page 3 of the response, that the specification demonstrates in vivo efficacy of treatment with compounds blocking IL-18. This argument is not persuasive for the following reasons: 1) the rejection is not based on the Dayer reference. 2) The Dayer reference does not represent the entire field, and what Dayer was not able to achieve does not indicate the same for others. 3) The Ho reference *expressly teaches* a method for treating conditions with excess Th1 production, such as autoimmune diseases including MS, RA, IDDM, IBD and psoriasis, by administering a composition comprising an anti-IL-18 antibody (the abstract, page 4, lines 7-10, and page 20, lines 19-24), indicating blocking IL-18 *in vivo*. With respect to the argument that neither Ho nor Torigoe quells the speculation regarding the *in vivo* effects of blocking IL-18 (no working example), "a reference is not limited to the disclosure of specific working examples" (*In re Mills*, 470 F.2d 649, 651, 176 USPQ 196, 198 (CCPA 1972)). Further, according to MPEP (§2121), "when the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980)".

It is further noted (with respect to the same argument (in vivo effect), and the argument that thus, at the time of filing, one of skill in the art could not reasonably conclude that blocking IL-18 in vivo by *targeting the IL-18R* would have efficacy in treating a medical disorder as claimed), that the instant specification does not disclose any working example of *in vivo targeting the IL-18R* either, and all working examples in the specification are directed to the use of IL-18BP. If the same logic in applicant's argument applies, the instant invention would have been in question as to its enablement since no working example of in vivo targeting the *IL-18R* is disclosed in the specification. However, such is not an issue because the state of the art in the field of cytokines, and receptors and antibodies thereof is high. Therefore, the issue whether in vivo targeting the IL-18R would be effective (as the art only teaches blocking IL-18 (not IL-18R) with the anti-IL-18 antibody) is less relevant. Given the fact that blocking IL-18 with the anti-IL-18 antibody can be used to treat the diseases/conditions (as taught by Ho), it would be instantly clear that the expectation of success in *in vivo* targeting the IL-18R would be high in the absence of evidence to the contrary.

Claim 7 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Ho et al., WO 00/56771 (28 September 2000), and in view of Torigoe et al., US6,600,022 B1, as applied to claims 1, 6, 9-12, 14 and 15 above, and further in view of Huston et al. (Proc. Natl. Acad. Sci., 1988, 85(16):5879-83), for the reasons of record set forth in the previous Office Actions mailed on 12/3/04 and 8/13/05.

Applicants argument filed on 02 June 2006 has been fully considered, but is not deemed persuasive for reasons below.

At page 2 of the response, the applicant argues that in light of the Ho and Torigoe references at the time of filing, one of skill in the art would not have had a reasonable expectation that an antibody binding the IL-18R would be successful in treating the indicated diseases, and that Huston fails to overcome the deficiencies of the other references. This argument is not persuasive for the same reasons above.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ho et al., WO 00/56771 (28 September 2000), and in view of Torigoe et al., US6,600,022 B1, as applied to

claims 1, 6, 9-12, 14 and 15 above, and further in view of Jacobs et al., US5,605,690, for the reasons of record set forth in the previous Office Actions mailed on 12/3/04 and 8/13/05.

Applicants argument filed on 02 June 2006 has been fully considered, but is not deemed persuasive for reasons below.

At pages 2-3 of the response, the applicant argues that in light of the Ho and Torigoe references at the time of filing, one of skill in the art would not have had a reasonable expectation that an antibody binding the IL-18R would be successful in treating the indicated diseases, and that Jacobs fails to overcome the deficiencies of the other references. This argument is not persuasive for the same reasons above.

Conclusion:

No claim is allowed.

Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
8/10/06

GARY B. NICKOL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600